IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civil Action No. 08-426 JJF Judge Joseph J. Farnan, Jr.

TEVA PHARMACEUTICALS USA, INC.'S
ANSWER AND AFFIRMATIVE DEFENSES

Defendant, Teva Pharmaceuticals USA, Inc. (hereinafter referred to as "Teva"), hereby answers Plaintiffs' Complaint for Patent Infringement and asserts its affirmative defenses as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. §§ 271(e) and (a). This action relates to an Abbreviated New Drug Application ("ANDA") filed and amended by and/or for the benefit of Teva Pharmaceuticals USA with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' highly successful Crestor® pharmaceutical products that are sold in the United States (the "Teva ANDA").

ANSWER:

Teva admits that the Complaint purports to state a claim arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. §§ 271(e) and

(a). Teva further admits that the Complaint purports to relate to an Abbreviated New Drug Application ("ANDA") filed and amended by and/or for the benefit of Teva with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Crestor® pharmaceutical products sold in the United States. Teva denies the remaining allegations in paragraph 1.

Parties

2. Plaintiff AstraZeneca Pharmaceuticals LP ("AstraZeneca") is a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803 USA.

ANSWER:

On information and belief, admitted.

3. Plaintiff AstraZeneca UK Limited is a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K 1LN, England.

ANSWER:

On information and belief, admitted.

4. Plaintiff IPR Pharmaceuticals, Inc. ("IPR") is a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

ANSWER:

On information and belief, admitted.

5. Plaintiff Shionogi Seiyaku Kabushiki Kaisha is a corporation operating and existing under the laws of Japan with its principal place of business at 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan.

ANSWER:

On information and belief, admitted.

6. On information and belief, Defendant Teva Pharmaceuticals USA[, Inc.] ("Teva") is a corporation operating and existing under the laws of Delaware with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

ANSWER:

Admitted.

Background

7. IPR is the holder of approved New Drug Application ("NDA") No. 021366 for Crestor® Tablets, in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms, containing rosuvastatin calcium. AstraZeneca is IPR's authorized agent for matters related to NDA No. 021366.

ANSWER:

Teva admits that, according to the Electronic Orange Book, IPR is the holder of approved New Drug Application ("NDA") No. 021366 for Crestor® Tablets, in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms, containing rosuvastatin calcium. Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 and, on that basis, denies them.

8. CRESTOR® (rosuvastatin calcium) is a prescription drug belonging to a group of medicines (called statins) that are used to treat high cholesterol. Crestor® is one of the most effective lipid-lowering statins available. Over 11 million patients have been prescribed Crestor®, and over 110 million prescriptions have been written worldwide for Crestor®.

ANSWER:

Teva admits that CRESTOR® (rosuvastatin calcium) is a prescription drug belonging to a group of medicines (called statins) that are used to treat high cholesterol. Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8 and, on that basis, denies them.

9. Plaintiffs, among other things, manufacture, market, promote, educate the public and physicians about, and conduct research and development on existing and new

indications for Crestor® Tablets. Plaintiffs financially benefit from sales of Crestor® Tablets in the United States.

ANSWER:

Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9 and, on that basis, denies them.

10. On information and belief, Teva filed with the FDA, in Rockville, Maryland, ANDA No. 79-166 under 21 U.S.C. §355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, which are generic versions of Plaintiffs' Crestor® Tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, respectively.

ANSWER:

Teva admits that it filed with the FDA, in Rockville, Maryland, ANDA No. 79-166 under 21 U.S.C. §355(j) to obtain FDA approval for the commercial manufacture, use, and sale in the United States of rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, which are bioequivalent to tablets marketed under the Crestor® trademark. Teva denies the remaining allegations in paragraph 10.

11. By letter dated October 29, 2007, Teva notified Plaintiffs that it had filed an ANDA seeking FDA approval to market rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths ("Teva Rosuvastatin Calcium Tablets"), and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

ANSWER:

Admitted.

12. By letter dated June 11, 2008, received by Plaintiffs on or about June 13, 2008 Teva notified Plaintiffs that it had amended its ANDA seeking FDA approval to market the Teva Rosuvastatin Calcium Tablets, and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

ANSWER:

Teva admits that, by letter dated June 11, 2008, Teva notified Plaintiffs that it had amended its ANDA seeking FDA approval to market rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95. Teva further admits that each of the plaintiffs received the letter by June 13, 2008, at the latest. Teva denies the remaining allegations in paragraph 12.

13. On information and belief, Teva is in the business of developing, manufacturing, marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.

ANSWER:

Teva admits that it is in the business of developing, manufacturing, marketing, distributing, and selling generic pharmaceutical products within the United States. Teva denies the remaining allegations in paragraph 13.

Jurisdiction and Venue

14. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER:

Teva admits that subject matter jurisdiction is proper with respect to Count I of Plaintiffs' Complaint under 28 U.S.C. §§ 1331 and 1338(a). Teva denies the remaining allegations in paragraph 14.

15. On information and belief, Teva develops and manufactures generic drugs and markets, distributes, and sells its generic drugs throughout the United States, including the State of Delaware.

ANSWER:

Teva admits that it develops and manufactures generic drugs and markets, distributes, and sells its generic drugs throughout the United States. Teva denies the remaining allegations in paragraph 15.

16. Personal jurisdiction over Teva is proper because it purposefully avails itself of the privilege of selling its generic products in the state of Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware. Among other things, upon information and belief, Teva places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware.

ANSWER:

Teva admits, for the purposes of this action only, that personal jurisdiction over Teva is proper. Teva denies the remaining allegations in paragraph 16.

17. Personal jurisdiction over Teva is proper because Teva is incorporated in Delaware and has purposely availed itself of the privilege of doing business in this State. Further, Teva maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

ANSWER:

Teva admits that it is incorporated in Delaware. Teva further admits, for the purposes of this action only, that personal jurisdiction over Teva is proper. Teva denies the remaining allegations in paragraph 17.

18. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

ANSWER:

Admitted.

Count I

Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(e)(2)

19. Plaintiffs incorporate by reference paragraphs 1-18 of this Complaint as if fully set forth herein.

ANSWER:

Teva incorporates by reference its answers to paragraphs 1-18 above as if fully set forth herein.

20. United States Patent No. RE37,314 ("the '314 patent"), entitled "Pyrimidine Derivatives," was duly and legally reissued by the United States Patent and Trademark Office on August 7, 2001. Plaintiffs hold all substantial rights in the '314 patent and have the right to sue for infringement thereof. A true and correct copy of the '314 patent is attached as Exhibit A.

ANSWER:

Teva admits that United States Patent No. RE37,314 ("the '314 patent"), entitled "Pyrimidine Derivatives," was issued by the United States Patent and Trademark Office on August 7, 2001. Teva further admits that Shionogi Seiyaku Kabushiki Kaisha is listed as the assignee on the face of the '314 patent. Teva further admits that what appears to be a true and correct copy of the '314 patent is attached as Exhibit A to the Complaint. Teva denies the remaining allegations in paragraph 20.

21. On information and belief, Teva amended ANDA No. 79-166 in order to obtain approval to market the Teva Rosuvastatin Calcium Tablets in the United States before the expiration of the '314 patent. On information and belief, Teva also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification letter alleging that the claims of the '314 patent are invalid, unenforceable, or not infringed.

ANSWER:

Admitted.

22. On information and belief, Teva does not assert that Teva Rosuvastatin Calcium Tablets fall outside the scope of claims 6 and 8 of the '314 patent.

ANSWER:

To the extent the claims of the '314 patent are valid and enforceable, Teva admits that, at this time, it does not assert that Teva Rosuvastatin Calcium Tablets fall outside the scope of claims 6 and 8 of the '314 patent. Teva denies the remaining allegations in paragraph 22.

23. Under 35 U.S.C. § 271(e)(2)(A), the submission by Teva to the FDA of amended ANDA No. 79-166 to obtain approval for the commercial manufacture, use, or sale of the Teva Rosuvastatin Calcium Tablets before the expiration date of the '314 patent constitutes infringement of one or more claims of the '314 patent, either literally or under the doctrine of equivalents.

ANSWER:

Teva admits that the act of filing ANDA No. 79-166 constituted a technical act of infringement under 35 U.S.C. § 271(e)(2)(A). Teva denies the remaining allegations of paragraph 23.

24. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

ANSWER:

Denied.

Count II

Declaratory Judgment of Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(a)

25. Plaintiffs incorporate by reference paragraphs 1-24 of this Complaint as if fully set forth herein.

ANSWER:

Teva incorporates by reference its answers to paragraphs 1-24 above as if fully set forth herein.

26. Upon information and belief, Teva has made substantial preparations to sell Teva Rosuvastatin Calcium Tablets labeled for the same dosages as the Crestor® products.

ANSWER:

Teva admits that it filed ANDA No. 79-166 to obtain FDA approval for the commercial manufacture, use, and sale in the United States of rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, which are bioequivalent to tablets marketed under the Crestor® trademark. Teva denies the remaining allegations in paragraph 26.

27. Upon information and belief, Teva intends to commence sale of Teva Rosuvastatin Calcium Tablets immediately upon receiving approval from the FDA.

ANSWER:

Teva admits that it filed ANDA No. 79-166 to obtain FDA approval for the commercial manufacture, use, and sale in the United States of rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, which are bioequivalent to tablets marketed under the Crestor® trademark. Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 27 and, on that basis, denies them.

28. The manufacture, importation, sale, and offer for sale of Teva Rosuvastatin Calcium Tablets, once approved by the FDA, will directly infringe, induce and/or contribute to the infringement of one or more claims of the '314 patent under 35 U.S.C. § 271(a).

ANSWER:

Denied.

29. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER:

Denied.

30. An actual controversy exists relating to Teva's threatened infringement of the '314 patent.

ANSWER:

Denied.

* * *

Teva further denies all remaining allegations that are not specifically admitted herein.

PRAYER FOR RELIEF

Teva denies that Plaintiffs are entitled to a judgment in their favor and denies that Plaintiffs are entitled to the relief requested.

AFFIRMATIVE DEFENSES

Further responding to Plaintiffs' Complaint, Teva asserts the following affirmative defenses and reserves the right to amend its Answer and Affirmative Defenses as additional information becomes available:

1. Teva does not infringe, and has not infringed, any valid and enforceable claim of the '314 patent, either literally or under the doctrine of equivalents.

2. The claims of the '314 patent are invalid and void for failure to comply with the requirements of Title 35, United States Code, including, but not limited to, one or more of Sections 102, 103 and/or 112.

3. Count II of the Complaint fails to state a claim upon which relief can be granted.

4. The Court lacks subject matter jurisdiction over Count II of the Complaint.

5. The Court should exercise its discretion to decline jurisdiction over Count II of the Complaint to the extent a sufficient case or controversy exists.

JURY DEMAND

Teva demands a jury on all issues triable by a jury, and specifically with respect to the claims raised in Plaintiffs' Complaint.

Respectfully submitted,

Dated: July 31, 2008

By: */s/ Joseph H. Huston, Jr.*

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Attorneys for Defendant,
TEVA PHARMACEUTICALS USA, INC.

CERTIFICATE OF SERVICE

I, Joseph H. Huston, Jr., hereby certify that, on this 31st day of July, 2008, and in addition to the service provided by the Court's CM/ECF system, true and correct copies of the foregoing *ANSWER AND AFFIRMATIVE DEFENSES* were served by first class United States mail, postage prepaid, upon the parties listed below:

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